

REMARKS

Claims 1, 5 and 8 are currently under examination. The currently outstanding office action sets forth rejections based on 35 U.S.C. §112, second paragraph and 35 U.S.C. §103. Applicants have amended claim 1 to specify that the units referred to are bacterial cells. Claim 8 has been amended to specify that it is the intestinal population of probiotic *Lactobacillus paracasei* that increases ten-fold. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the pending claims are allowable, and reconsideration is respectfully requested.

1. The Claims as amendment satisfy the Requirements of 35 U.S.C. 112, Second Paragraph

Claims 1, 5 and 8 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. According to the Examiner, Claim 1, and claims dependent upon claim 1, are rendered indefinite for reciting “ 1×10^6 or higher per gram” without specifying the units. In response, Claim 1 has been amended to recite the units, i.e., bacterial cells per gram.

The Examiner maintains that claim 8 is indefinite for reciting “in amounts sufficient of table olives to increase one logarithmic cycle the intestinal population of the probiotic bacteria population” because it is not clear whether it is the population of the bacteria adhered to the table olives, or some other probiotic population of bacteria, that increases. In response, claim 8 has been amended to specify that it is the intestinal population of probiotic *Lactobacillus paracasei* that increases ten-fold.

In view of applicants’ amendments to the claims it is respectfully request withdrawal of the rejections under §112, second paragraph.

2. The Claims Are Not Rendered Obvious by the Cited Prior Art

Claims 1, 5 and 8 are rejected under 35 U.S.C. §103 as being unpatentable over Suskovic et al. (Food Technol. Biotechnol. 1997, 35:107-112; “Suskovic”), in view of Betoret (Journal of Food Engineering 56:273-277:”Betoret”) and Reid (US2001/0036453: “Reid”). According to the Examiner, Suskovic teaches olives that are prepared with probiotic *Lactobaccilus* spp. Although the reference does not specifically teach that the cells adhere to the pericarp of the

olives, Betoret is said by the Examiner to teach methods for preparing fruits in order to ensure adherence of probiotic bacteria. Further, Reid is alleged by the Examiner to teach methods for administration of probiotic *Lactobacillus* to subjects and that the lactobacilli colonize the intestines of patients. According to the Examiner, it would have been obvious to combine the cited teachings of the prior art to arrive at the claimed invention with a reasonable expectation of success.

For reasons detailed below, the claims are not rendered obvious by the cited references.

A claim is invalid if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). The consistent criterion of determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124 (Fed. Cir. 2000).

The present invention is based on the surprising result that probiotic bacteria adhere to the pericarp of the olives in levels sufficient to exert a beneficial action on the gastro-intestinal tract of a subject. As set forth in Example 1 of the specification, when olives are stored in brine containing lactobacilli and/or bifidobacteria for three months, removed from the brine and tested for adherence of bacteria to the pericarp, it is observed that the pericarp allows for tight anchorage of the bacteria. (See, Table 1 and 2). Additionally, as set forth in Example 3 of the specification, a sufficient number of probiotic bacteria adhere to the surface of the olives of the invention so that following ingestion the population of bacteria in human subjects increases about two logarithmic cycles. Following suspension of ingestion of the olives, the levels of the probiotic bacteria decrease, demonstrating a correlation between the ingestion of the olives of the invention and the increased presence of probiotic bacteria in the gastrointestinal tract.

Applicants maintain that Suskovic merely discloses studies relating to the testing of the resistance properties of *Lactobacillus plantarum* L4 to antibiotics, lysozyme, and salts of bile. A review of Suskovic indicates that the reference fails to teach, or even suggest, that *Lactobacillus* can adhere to the pericarp of olives in amounts sufficient to provide a probiotic nutritional benefit. In fact, the only mention of olives in the Suskovic reference is found in the first line of

the abstract which states that *Lactobacillus plantarum* is used as a starter culture for olive conservation.

Further, the teaching, or suggestion, that is missing from Suskovic, i.e. that *Lactobacillus* can adhere to the pericarp of olives in amounts sufficient to provide a probiotic nutritional benefit, which is the very basis of the presently claimed invention, is not supplied by either of the two additionally recited references. Betoret merely discloses that freeze dried apples can be impregnated with *Lactobacillus*. The impregnation of freeze dried apples is completely different from the simple coating of olives. There is absolutely no teaching in Betoret that *Lactobacillus* adheres to olives in amounts sufficient to provide a probiotic nutritional benefit. Further, Reid merely discloses that selected probiotic organisms can provide protection against intestinal infection in newborns. Thus, Reid also fails to disclose, or suggest, that *Lactobacillus* can adhere to the pericarp of olives.

Thus, given the differences between the disclosures of Suskovic, Betoret and Reid and the presently disclosed invention, the claims simply cannot be anticipated, or rendered obvious, by Suskovic, Betoret or Reid. Applicants maintain that the prior art simply does not disclose, nor would it have suggested to one of ordinary skill in the art, that olives stored in brine containing lactobacilli would have said bacteria adhered to their pericarp in levels greater than 1×10^6 .

Finally, the cited references fail to provide the reasonable likelihood of success that is required for maintenance of a obviousness rejection. The references fail to provide to one of skill in the art a reasonable expectation of success that olives could be coated with the probiotic bacteria *Lactobacillus* in an amount of 1×10^6 or higher per gram of olive and that upon ingestion that the bacteria could increase at least one logarithmic cycle the intestinal population of the probiotic bacteria.

Thus, Applicants respectfully request withdrawal of the rejections under §102 (b) or §103.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, early notice of which is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

If any fees are required in connection with the filing of this amendment, the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

Date: May 23, 2011

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